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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,003	11/17/2003	Tianming Chen	7678.804.1.2	2264

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EXAMINER

ROBERTS, LEZAH

ART UNIT PAPER NUMBER

1614

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/715,003	<b>Applicant(s)</b> CHEN, TIANMING	
	<b>Examiner</b> Lezah W. Roberts	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____.  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>a &amp; b</u> .   | 6) <input type="checkbox"/> Other: ____.                                    |

## DETAILED ACTION

### *References*

The examiner did not consider references 101-109 because the applicant did not provide copies of the references.

### *Claims*

#### **Claim Rejections - 35 USC § 102 - Anticipation**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 6, 9, 10, 12-28 and 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Sagel et al. (US 5,891,453).

Sagel et al. teaches a system for delivery of a tooth whitening substance comprising a bleaching composition and strip suitable for placement to a plurality of adjacent teeth. The preferable form of the composition is a gel (col. 7, lines 58-61). The bleaching composition is placed on a strip able to stay on the teeth with minimum slippage. Possible tooth whitening actives include peroxides, such as hydrogen peroxide and carbamide peroxide; as well as metal chlorites, perborates, percarbonates, and peroxyacids. The tooth whitening active is present in an amount of from about 0.01% to 40%, by weight of the substance. The gelling agent used in the

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invention makes up 0.1 to about 15% by weight of the composition.

Carboxypolymethylene is the primary gelling agent taught in the reference but other gelling agents that can be used to improve the adhesiveness of the composition to the tissues of the oral cavity include polyvinylpyrrolidone (PVP) with a molecular weight of about 50,000 to about 300,000. Several examples were disclosed using different polymers as the gelling agents and secondary agents, such as xanthan gum and Guar gum, in the composition. It is anticipated that the PVP can replace the carboxypolymethylene as the gelling agent in the bleaching composition. One of the compositions included glycerin and water. The water component can make up 0.1 to 95% weight of the composition. The pH adjusting agents used in the gel composition to optimize its storage stability and to make it safe for oral tissue include sodium citrate, which is an example of a desensitizing agent in the instant claims. The strip material serves as a protective barrier to substantially prevent saliva contacting the tooth whitening substance and leaching and/or erosion of the tooth whitening substance from the surface of the teeth by the wearer's lips, tongue, and other soft tissue. The strip of material may comprise materials such as polymers. Suitable polymers include, but are not limited to, polyethylene, ethylvinylacetate, ethylvinyl alcohol, and polyesters. The strip of material is generally less than about 1 mm thick and preferably, the shape of the strip of material is any shape that has rounded corners. The strip of material may contain shallow pockets and has a flexural stiffness of less than about 5 grams/cm; as measured on a Handle-O-Meter, model #211-300, available from Thwing-Albert Instrument Co. of Philadelphia, Pa., as per test method ASTM D2923-95; preferably

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from about 0.1 grams/cm to about 1 grams/cm. The strip of material is held in place on a plurality of adjacent teeth by adhesive attachment provided by the substance. The viscosity and general tackiness of the substance cause the strip of material to be adhesively attached to a plurality of adjacent teeth without substantial slippage under the potential friction from the lips, tongue, and other soft tissue rubbing against the strip of material during mouth movements associated with talking, drinking, etc (col. 5, line 33 – col.7, line 6). The delivery system also comprises a release liner (see claims). The reference anticipates the instant claims insofar as to disclose a delivery system for a tooth whitening compositions comprising teeth whitening composition delivered to the teeth by a water-impermeable strip.

**Claim Rejections - 35 USC § 103 – Obviousness**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sagel et al. in view of Venema et al. (US 5,670,138).

The primary reference is discussed above. The reference differs from the instant claims insofar as to not disclose polyvinyl having a molecular weight of 1,000,000 to 1,500,000.

Venema et al. teaches mouth care products comprising of N-vinylpyrrolidone and acrylic acid copolymers of high molecular weight as additives and carrier material in mouth-care products. Numerous attempts have been made to improve the effectiveness of the bactericides and the other active components of mouth care products, such as fluoride. These attempts were usually based on enhancing the bioadhesion of the active components in the mouth, by the addition of polymers to the products. The improved bioadhesion in the oral care products can be obtained by the use of polymers having an interaction with both the active substance and the glycoproteins (mucines). This may result in an enhanced substantivity that is an improved availability, at the same time resulting in a prolonged retention time of the active component. An example of a known polymer resulting in improved bio-adhesion is polyvinylpyrrolidone. Copolymers having higher molecular weights tend to have a more pronounced effect although it is preferred not to use molecular weights of over 1,000,000, the upper limit. This is dependent on the production process of the copolymer. The reference differs from the instant claims insofar as to not disclose using a high molecular weight polymer in a teeth whitening gel composition.

It would have been obvious to one of ordinary skill in the art to have made polyvinylpyrrolidone with higher molecular weights to incorporate into the gel composition of the primary reference motivated by the desire to improve bioadhesion to the teeth and enhance substantivity of the whitening composition.

**Obviousness – Type Double Patenting**

Claims 1-33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,730,316. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass using the same bleaching composition and a tray or strip for bleaching a person's teeth. The differences between the patented claims and the instant claims are the instant claims recite specific % weight compositions of the liquid component, which are found in the disclosure of the patent; the composition is a one-part composition, which is implied by the patented claims; the composition is a gel whereas the patent claims describe the composition as viscous and tacky yet sufficiently flowable; the barrier is a water-resistant barrier layer, in which the disclosure of the patent states the strip is made of a water impermeable material; and the composition is formulated to release hydrogen peroxide as the primary or sole bleaching agent, which would be an inherent property because the compositions are the same according to the respective disclosures. It would have been obvious to use the liquid percentages recited in the instant claims based on the disclosure of the patent.

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Claims 1-33 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lezah Roberts  
Patent Examiner  
Art Unit 1614



Frederick Krass  
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